MAR 2 4 2004

K040051

510(k) Summary

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR¶807.92(a).

807.92(a)(1)

Submitter Information

Name:	Eagle Technology, Inc.
Address:	1-2-23 Hirosaka, Kanazawa, Ishikawa, Japan 920-1331
Phone:	+81-76-263-3636
Facsimile:	+81-76-294-6745
Contact Person:	Hideyuki Fujihira
Date:	1/5/2004

807.92(a)(2)

Trade Name:	MEGvision EQ1000C Series
Common Name:	Magnetoencephalographic (MEG) Device
Classification Name(s):	Electroencephalograph
Classification Number:	21CFR882.1400 OLX, OLY

807.92(a)(3)

Predicate Device(s)

Device Name	510(k) #	Manufacturer
CTF "Whole-Cortex MEG System"	K971329	CTF Systems, Inc.
Neuromag-122	K962764	Neuromag Ltd.

3 pages

Eagle Technology, Inc.

807.92 (a)(4)

Device Description

The MEGvision integrates up to 320 dc-SQUID axial gradiometer with PCs and data acquisition software in order to measure the magnetic signals generated by the intercellular dendritic currents. These detectors positioned in a helmet shaped array give the user the ability to record the electrical activity of the entire surface of the brain cortex simultaneously without having to move the position of the sensor array.

807.92(a)(5)

Intended Use(s)

The MEGvision non-invasively measures the magnetoencephalographic (MEG) signals produced by the electrical activities by the tissue activities of the brain. These signals, position, direction, and sensitivity of the sensors are acquired and displayed, and may be interpreted by trained clinicians to help localize these active areas. The locations may be correlated to anatomical structure of the brain.

807.92(a)(6)

Technological Characteristics

TABLE 1.1 Comparison to the Predicate Devices

	Eagle Technology, Inc. MEGvision	CTF Systems, Inc. "Whole-Cortex MEG System" (K971329)	Neuromag Ltd. "Neuromag-122" (K962764)
No. of SQUID detectors/ channels for MEG data:	64 to 320	64 to 200	122
Operating Principle	Superconducting flux transformer coupled with dc-SQUID driven by digitally controlled analog flux locked loop circuit	Superconducting flux transformer coupled with dc-SQUID controlled by digital flux-locked loop	Superconducting flux transformer coupled with dc-SQUID controlled by analog flux-locked loop
No. of auxiliary channels for other types of data	166	88	166
Gradiometer:	1 axial first order gradiometer per location	1 axial first order gradiometer per location	2 orthogonal planar first order gradiometers per location
Intersensor spacing	20mm to 25mm (160 sensor configuration)	32 mm (150 sensor configuration)	43-44 mm
Gradiometer placement	64 to 320 location distributed across the helmet shaped lower tip of a dewar	64 to 200 locations distributed across the helmet shaped lower tip of a dewar (optional Caucasian or Oriental head shape)	61 locations distributed across the helmet shaped lower tip of a dewar.

	Eagle Technology, Inc. MEGvision	CTF Systems, Inc. "Whole-Cortex MEG System" (K971329)	Neuromag Ltd. "Neuromag-122" (K962764)
Cryogen used:	Liquid helium	Liquid helium	Liquid helium
Coverage	One acquisition to cover entire head	One acquisition to cover entire head	One acquisition to cover entire head
Gantry	Floor mounted fixed gantry.	Floor mounted, standard gantry is fixed. Optional gantry tilts to 90 degrees	Floor mounted, standard gantry tilts up to 30 degrees. Optional gantry tilts to 45 degrees
Patient Position	Lying on back	Seated, or lying on back with optional bed	Seated or supine. Optional chair insert for children
Head Position Indicator	Included	Included	Available
Computer	Personal Computer with Wind	HP workstation with UNIX environment	HP workstation with UNIX environment
Networking Capabilities	Ethernet connections to other network system available	Ethernet connections to other workstations included	Ethernet connections to other workstations available
Magnetically Shielded Room Accessories	Interior DC lights, video camera and two-way intercom for patients	Interior DC lights, video camera and monitor and two-way intercom for monitoring patients	Video monitor and two-way intercom for monitoring patients
Intended Use	The **MEGvision** is intended for use as a magnetoencephalographic (MEG) device which non-invasively detects and displays biomagnetic signals produced by electrically active nerve tissue in the brain. When interpreted by a trained clinician, the data enhances the diagnostic capability by providing useful information about the location relative to brain anatomy of active nerve tissue responsible for critical brain functions.	The **CTF "Whole-Cortex MEG System"**, is intended for use as a magnetoencephalographic (MEG) device which non-invasively detects and displays biomagnetic signals produced by electrically active nerve tissue in the brain. When interpreted by a trained clinician, the data enhances the diagnostic capability by providing useful information about the location relative to brain anatomy of active nerve tissue responsible for critical brain functions.	The **Neuromag-122 system** is intended for use as a magnetoencephalographic (MEG) device which non-invasively detects and displays biomagnetic signals produced by electrically active nerve tissues in the brain. When interpreted by a trained clinician, the data enhances the diagnostic capability by providing useful information about the location relative to brain anatomy of active nerve tissue responsible for critical brain functions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Eagle Technology, Inc.
c/o Mr. Lewis Fisher
Eagle Technology North America, LLC
25 Bisbee Court, Suite B
Santa Fe, New Mexico 87508

Re: K040051
Trade/Device Name: MEGvision EQ 1000C Series
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLX, OLY
Dated (Date on orig SE ltr): January 5, 2004
Received (Date on orig SE ltr): January 12, 2004

APR - 9 2012

Dear Mr. Fisher:

This letter corrects our substantially equivalent letter of March 24, 2004.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Keoia Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040051

Device Name: MEGvision EQ1000C Series

Indications For Use: The MEGvision is intended for use as a magnetoencephalographic (MEG) device which non-invasively detects and displays biomagnetic signals produced by electrically active nerve tissue in the brain. When interpreted by a trained technician, the data enhances the diagnostic capability by providing useful information about the location relative to brain anatomy of active nerve tissue responsible for critical brain functions.

Prescription Use XX **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C Provost
(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K040051